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APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/945,145 08/31/2001		Robert S. Matson	1984-045	3127	
22471	7590 07/29/2004		EXAMINER		
PATENT L	EGAL DEPARTMEN	LU, FRANK WEI MIN			
	COULTER, INC. RBOR BOULEVARD	ART UNIT	PAPER NUMBER		
BOX 3100		1634			
FULLERTO	N, CA 92834-3100	DATE MAILED: 07/29/2004			

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applica	tion No	Applicant(s)				
Office Action Summary		09/945,		MATSON, ROBERT S.				
		Examin		Art Unit				
The MAI	LINC DATE of this commun	Frank V		1634	Idraga			
Period for Reply	LING DATE of this commu	nication appears on น	ne cover sneet with the d	correspondence ad	aress			
THE MAILING [- Extensions of time rafter SIX (6) MONT - If the period for repl - If NO period for repl - Failure to reply with Any reply received by	O STATUTORY PERIOD F DATE OF THIS COMMUN may be available under the provision HS from the mailing date of this com y specified above is less than thirty (y is specified above, the maximum s in the set or extended period for repl by the Office later than three months adjustment. See 37 CFR 1.704(b).	IICATION. s of 37 CFR 1.136(a). In no of munication. 30) days, a reply within the si tatutory period will apply and y will, by statute, cause the a	event, however, may a reply be tir atutory minimum of thirty (30) day will expire SIX (6) MONTHS from oplication to become ABANDONE	nely filed /s will be considered timel the mailing date of this co ED (35 U.S.C. § 133).				
Status	,							
1)⊠ Responsi	ve to communication(s) fil	ed on 06 Anril 2004						
	Responsive to communication(s) filed on <u>06 April 2004</u> . This action is FINAL . 2b)⊠ This action is non-final.							
· <u>=</u>	<u>'</u>							
-	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Clai	·	2/1 / 2/1	,,					
<u> </u>		P 1 - 41 P P -						
	Claim(s) 1-32 and 34-72 is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
· <u> </u>	Claim(s) is/are allowed.							
· _ · · · ·	Claim(s) 1-32 and 34-72 is/are rejected.							
· <u> </u>	Claim(s) is/are objected to. Claim(s) are subject to restriction and/or election requirement.							
o) Claim(s) _	are subject to restri	ction and/or election	requirement.					
Application Papers	S							
9)⊠ The specif	ication is objected to by th	ne Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11)☐ The oath o	or declaration is objected t	o by the Examiner. I	Note the attached Office	Action or form PT	O-152.			
Priority under 35 L	J.S.C. § 119							
a)∐ All b)[1.∐ Cer	Igment is made of a claim ☐ Some * c) ☐ None of: tified copies of the priority tified copies of the priority	documents have be	een received.					
3.☐ Cor	pies of the certified copies	of the priority docum	nents have been receive	ed in this National	Stage			
•	lication from the Internation	•			•			
* See the atta	ached detailed Office action	on for a list of the ce	rtified copies not receive	ed.				
Attachment(s)			_					
1) Notice of Reference		BTO 048)	4) Interview Summary Paper No(s)/Mail D					
	rson's Patent Drawing Review (I sure Statement(s) (PTO-1449 o		5) Notice of Informal F		D-152)			
Paper No(s)/Mail [,	6) Other:					

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on April 6, 2004 has been entered. The claims pending in this application are claims 1-32 and 34-72. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Specification

2. The disclosure is objected to because of the following informality: there is no BRIEF DESCRIPTION OF THE DRAWINGS in the specification.

Appropriate correction is required.

Claim Objections

3. Claim 8 is objected to because of the following informality: "PNA" is an abbreviation. It can only be used after this phrase appears once.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-32 and 34-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention.

To the extent that the claimed methods are not described in the instant disclosure, claims 1-32 and 34-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

The recitation "wherein said probe biopolymer is applied to dots individually in said microarray" is added to the newly amended independent claims 1, 30, and 53. Although the specification describes that the sample aliquots are dispensed on a substrate as an array of small dots (page 8, second paragraph) and the first element of the microarray is contacted with a first known probe and second element of the microarray is contacted with a second known probe (see page 14, third paragraph), the specification fails to define or provide any disclosure to support such claim recitation wherein said probe biopolymer (one probe) is applied to dots individually in said microarray.

MPEP 2163.06 notes "If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE

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WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 7. Claims 1-32 and 34-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 8. Claims 1, 30, and 53 are rejected as vague and indefinite in view of the step (c) of the claim because detecting the presence of said complex cannot measurement of the amount of said nucleic acid in said sample. The measurement of the amount of said nucleic acid in said sample require to quantitatively measure amount of said complex. Please clarify.
- 9. Claim 10 recites the limitation "said target polynucleotide" in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no target polynucleotide in claims 1 and 10. Please clarify.
- 10. Claims 22-27 are rejected as vague and indefinite because claims 22-27 lack antecedent basis since claim 1 only requires one probe while claims 27-27 require two or more probes.

 Please clarify.
- 11. Claims 45-50 are rejected as vague and indefinite because claims 45-50 lack antecedent basis since claim 30 only requires one probe while claims 45-50 require two or more probes.

 Please clarify.

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12. Claims 67-70 are rejected as vague and indefinite because claims 67-70 lack antecedent basis since claim 53 only requires one probe while claims 67-70 require two or more probes.

Please clarify.

Conclusion

13. No claim is allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu PSA

July 23, 2004

PRANKLU ATTENT EXAMINER

Tule on